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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,471	09/19/2001	Francois Mach	23135-501 CIP (NOV-1 CIP)	6761

30623 7590 12/17/2002

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,471	Applicant(s) MACH, FRANCOIS	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5-7, 10-11, 16-26 (in part) and 12, drawn to a method to achieve MHC-class II mediated immunomodulation in a mammal suffering from automimmune diseases such as diabetes, classified in class 514, subclass 311, 423, 460, and 510.

II. Claims 3, 5-7, 10-11, 16-26 (in part) and 12, drawn to a method to achieve MHC-class II mediated anti-inflammatory effect in a mammal suffering from automimmune diseases such as diabetes, classified in class 514, subclass 311, 423, 460, and 510.

III. Claims 4, 5-7, 10-11, 16-26 (in part) and 12, drawn to a method to achieve CD40 mediated anti-inflammatory effect in a mammal suffering from automimmune diseases such as diabetes, classified in class 514, subclass 311, 423, 460, and 510.

IV. Claims 1, 2, 5-7, 10-11, 16-26 (in part) and 13-14, drawn to a method to achieve MHC-class II mediated immunomodulation in a mammal under treatment in preparation of an organ or tissue transplantation, classified in class 514, subclass 311, 423, 460, and 510.

V. Claims 3, 5-7, 10-11, 16-26 (in part) and 13-14, drawn to a method to achieve MHC-class II mediated anti-inflammatory effect in a mammal

under treatment in preparation of an organ or tissue transplantation, classified in class 514, subclass 311, 423, 460, and 510.

VI. Claims 4, 5-7, 10-11, 16-26 (in part) and 13-14, drawn to a method to achieve CD40 mediated anti-inflammatory effect in a mammal under treatment in preparation of an organ or tissue transplantation, classified in class 514, subclass 311, 423, 460, and 510.

VII. Claims 1-2, 5-7, 10-11, 16-26 (in part) and 15, drawn to a method to achieve MHC-class II mediated immunomodulation in a mammal suffering from psoriasis or inflammation, classified in class 514, subclass 311, 423, 460, and 510.

VIII. Claims 3, 5-7, 10-11, 16-26 (in part) and 15, drawn to a method to achieve MHC-class II mediated anti-inflammatory effect in a mammal suffering from psoriasis, classified in class 514, subclass 311, 423, 460, and 510.

IX. Claims 4, 5-7, 10-11, 16-26 (in part) and 15, drawn to a method to achieve CD40 mediated anti-inflammatory effect in a mammal suffering from psoriasis, classified in class 514, subclass 311, 423, 460, and 510.

X. Claims 27-28, drawn to a method fro identifying molecules that inhibit IFN-induced CIITA expression, classified in class 435, subclass 1+.

XI. Claims 29-30, drawn to a method for identifying molecules that inhibit CD-40 expression, classified in class 435, subclass 1+.

XII. Claims 31-33, 36-46, drawn to a method of treating a patient afflicted with an autoimmune disease with HMG-CoA reductase inhibitor, classified in class 514, subclass 311, 423, 460, and 510.

XIII. Claim 34-35, drawn to a method of treating a patient in preparation for organ transplantation with a compound with HMG-CoA reductase inhibition and MHC Class II expression, classified in class 514, subclass 311, 423, 460, and 510.

XIV. Claims 47-48, 60-63, drawn to use of a statin to treat immuno-inflammatory disease, classified in class 514, subclass 311, 423, 460, and 510.

XV. Claim 49 and 68-75, drawn to a method of preventing or treating tissue or organ rejection with a compound capable in inhibiting IFN-γ inducible MHC class II expression and/or CD40 expression, classified in class 514, subclass 1+.

XVI. Claims 50-59, drawn to a method of treating a tissue graft, classified in class 514, subclass 311, 423, 460, and 510.

XVII. Claims 64-67, drawn to a kit, classified in class 424, subclass 400+.

XVIII. Claims 76-84, drawn to a method of treating an inflammatory disorder with a compound capable in inhibiting IFN-γ inducible MHC class II expression and/or CD40 expression, classified in class 514, subclass 311, 423, 460, and 510.

XIX. Claims 85-92, drawn to use of a statin to treat inflammatory skin disorder, classified in class 514, subclass 311, 423, 460, and 510.

XX. Claim 93, drawn to use of a statin to treat inflammatory ocular disorder, classified in class 514, subclass 311, 423, 460, and 510.

The inventions are distinct, each from the other because of the following reasons:

Inventions XVII **and** I-IX, XII-XVI, XVIII-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating diseases can be practiced with materially different products such as anti-inflammatory and corticosteroids.

Inventions I-IX, XII-XVI, XVIII-XX **and** X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The inventions X and XI function to identify compounds for different and distinct inhibitions of immunological activities, namely inhibition of IFNγ inducible MHC Class II expression and CD40 expression; while the inventions I-IX, XII-XVI, XVIII-XX function to treating various distinct and different disorders or medical conditions.

Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different functions. As discussed above, the invention X functions to identify a compound that inhibits IFNγ inducible MHC Class II expression; while the invention XI functions to identify a compound that inhibits CD40 expression.

Inventions I-IX, XII, XIII and XV, XIV and XVIII, XVI, XIX, and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The inventions of Group I-XI function to achieve immunological response, the invention of Group XII functions to treating autoimmune diseases, the inventions of Group XIII and XV function to treat organ rejection, the inventions of Group XIV and XVIII function to treat immuno-inflammatory disease, the invention of Group XVI functions to treat graft tissue, the invention of Group XIX function to treat inflammatory skin disease, and the invention of Group XX functions to treat inflammatory ocular disease.

Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and modes of operation. The inventions of Group I, IV, and VII function to achieve MHC Class II mediated immunomodulation in different patient populations. Among the inventions of

Group I, IV, and VII, the modes of operation are different in each group since they are treating different patients with different medical disorders or conditions such as autoimmune disorders, organ or tissue transplantation, or inflammatory disease. The inventions of Group II, V, and VIII function to achieve MHC Class II mediated anti-inflammatory effect in different patient populations. Among the inventions of Group II, V, and VIII, the modes of operation are different in each group since they are treating different patients with different medical disorders or conditions such as autoimmune disorders, organ or tissue transplantation, or inflammatory disease. The inventions of Group III, VI, and IX function to achieve CD40-mediated and anti-immunoinflammation in different patient populations. Among the inventions of Group III, VI, and IX, the modes of operation are different in each group since they are treating different patients with different medical disorders or conditions such as autoimmune disorders, organ or tissue transplantation, or inflammatory disease.

Inventions XIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group XIII functions to treat patient in preparation for organ transplantation with a compound with HMG-CoA reductase inhibition and MHC Class II expression. The invention of Group XV functions to prevent and treat organ rejection with a compound capable in inhibiting IFN-γ inducible MHC class II expression and/or CD40 expression.

Inventions XIV and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group XIV functions to treat immuno-inflammatory disease by employing a statin; while the invention of Group XVIII functions to treat an inflammatory disorder with a compound capable in inhibiting IFN-γ inducible MHC class II expression and/or CD40 expression.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
December 11, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

12/11/02